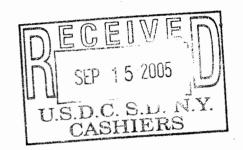
JUDGE BUCHWALD

05 CV 8015

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UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

SECURITIES AND EXCHANGE COMMISSION,

Plaintiff,

-against-

RODNEY R. DRINEN, GERALD R. HOLMES, THOMAS P. MCHUGH, NANCY M. MCHUGH, PRESCOTT B. NASH, and CHRISTINA H. NASH,

Defendants.

: CIVIL ACTION NO.

COMPLAINT FOR INJUNCTIVE AND OTHER RELIEF

Plaintiff Securities and Exchange Commission ("Commission"), for its Complaint against

Rodney R. Drinen ("Drinen"), Gerald R. Holmes ("Holmes"), Thomas P. McHugh ("T.

McHugh"), Nancy M. McHugh ("N. McHugh"), collectively ("the McHughs"), Prescott B. Nash ("P. Nash") and Christina H. Nash ("C. Nash") collectively ("the Nashs") alleges as follows:

OVERVIEW

- 1. This matter involves insider trading in the securities of CryoLife, Inc. ("CryoLife") by four CryoLife employees, two of their spouses and one additional family member. CryoLife preserves and sells implantable human tissue.
- 2. The material, non-public information concerned CryoLife's nationwide quality assurance shipping hold ("QA Hold") in response to receiving an Order for Retention, Recall, and/or Destruction ("Recall Order") issued by the Food and Drug Administration ("FDA") on August 13, 2002.
- 3. The Recall Order required CryoLife to stop distributing any human tissue that CryoLife had processed between October 3, 2001 and August 13, 2002, and to recall any such tissue previously distributed.
- 4. The employees, spouses and family member sold CryoLife stock, and/or bought PUT options on that stock on August 14, 2002, before the public learned of the QA Hold or Recall Order.
- 5. When CryoLife publicly disclosed the QA Hold and Recall Order, the price for its common stock plummeted until the New York Stock Exchange ("NYSE") halted trading. At that point, CryoLife's stock was trading at \$5.50 per share, down 42% from the prior day's closing share price of \$9.50.

- 6. Through their conduct, the Defendants collectively obtained ill-gotten gains and/or avoided losses, and caused their tippee to obtain ill-gotten gains and avoid losses, totaling approximately \$136,335.
- 7. By their conduct, Defendants have engaged in, and unless restrained and enjoined by this Court, will continue to engage in acts and practices which constitute and will constitute violations of Section 17(a) of the Securities Act of 1933 ("Securities Act") [15 U.S.C. 77q(a)] and Section 10(b) of the Securities Exchange Act of 1934 ("Exchange Act") [15 U.S.C. 78j(b)] and Rule 10b-5 thereunder [17 C.F.R. 240.10b-5].

JURISDICTION AND VENUE

- 8. This Court has jurisdiction of this action under Sections 20(b), 20(d) and 22(a) of the Securities Act [15 U.S.C. 77t(b), 77t(d) and 77v], and Sections 21(d), 21(e), 21A and 27 of the Exchange Act [15 U.S.C. 78u(d), 78u(e), 78u-1 and 78aa].
- 9. Venue is proper in this district pursuant to 28 U.S.C. § 1391(b)(1) and (2); Section 22(a) of the Securities Act [15 U.S.C. § 77v(a)]; and Section 27 of the Exchange Act [15 U.S.C. § 78aa]. Certain of the actions set forth herein that constitute violations of the Securities Act and the Exchange Act occurred within the Southern District of New York.

THE DEFENDANTS

10. Rodney R. Drinen resides in Phoenix, Arizona, and was a salesman in CryoLife's Mountain Region prior to being promoted to regional manager in November 2002. During August 2002, he reported to P. Nash.

- 11. Gerald R. Holmes resides in Blue Springs, Missouri, and was a salesman in CryoLife's Mountain Region during the relevant time. During August 2002, he reported to P. Nash.
- 12. Thomas P. McHugh resides in Hollis, New Hampshire, and was a salesman in CryoLife's Northeast Region during the relevant time.
- 13. Nancy M. McHugh was Thomas P. McHugh's wife during the relevant time and resides in Hollis, New Hampshire.
- 14. Prescott B. Nash resides in Englewood, Colorado, and was CryoLife's Mountain Region manager until he was terminated on September 3, 2002 as part of a company-wide layoff. In August 2002, Drinen and Holmes were among the salespeople who reported to him.
- 15. Christina H. Nash was P. Nash's wife during the relevant time and also resides in Englewood, Colorado.

THE COMPANY

- 16. CryoLife is a Florida corporation headquartered in Kennesaw, Georgia. The company claims to be a leader in the development, preservation and commercialization of implantable living human tissues for use in cardiovascular, vascular and orthopaedic surgeries throughout the United States and Canada. Additionally, CryoLife develops and commercializes implantable medical devices.
- 17. CryoLife's stock is registered pursuant to Section 12(b) of the Exchange Act.

 During the relevant period, CryoLife's stock was listed on the NYSE and PUT and CALL

 options on CryoLife's stock were traded on the Chicago Board Options Exchange.

THE RECALL ORDER

- 18. On or about November 7, 2001, a 23-year old Minnesota man died after receiving infected tissue during reconstructive knee surgery. The tissue had come from a donor and had been processed by CryoLife on or after October 3, 2001.
- 19. In response, in December 2001, the FDA and the Centers for Disease Control and Prevention ("CDC") began a joint investigation into CryoLife's practices. In January 2002, both agencies notified CryoLife that its inspections had concluded that the death in November 2001 was related to an infection from tissue processed by CryoLife. The CDC subsequently issued remedial recommendations to CryoLife.
- 20. During March and April 2002, after becoming aware of other patients becoming infected by CryoLife's products, the FDA conducted a second investigation of CryoLife. The FDA concluded that CryoLife's handling of certain tissue received and distributed by it might have been in violation of federal regulations.
- 21. On or around June 17, 2002, unsatisfied by CryoLife's responses to both of its investigations, the FDA issued a Warning Letter to CryoLife. The Warning Letter cautioned that, if CryoLife did not "take prompt action to correct these deviations," the FDA could "take additional . . . action without . . . notice, including, but not limited to, seizure, injunction, civil penalties, and/or an Order for Retention Recall and/or Destruction."
- 22. On or around June 24, 2002, CryoLife disclosed the Warning Letter to the public. The first two days after the Warning Letter was disclosed, CryoLife's stock price dropped from \$23.84 to \$15.30 per share, a 36% decline.

- On Tuesday, August 13, 2002, after the stock market closed, the FDA informed CryoLife that the FDA had issued the Recall Order covering the majority of CryoLife's tissue products. The Recall Order directed CryoLife to cease distributing human tissue that CryoLife had processed between October 3, 2001 and August 13, 2002, and recall any such tissue previously distributed, because CryoLife could not ensure that such tissue was free from contamination.
- 24. Later during the evening of August 13, 2002, as a result of the Recall Order, CryoLife's senior management instructed CryoLife's shipping and customer service departments to place a hold on all outbound tissue shipments and to recall recently shipped tissue products, including those already delivered to customers.
 - 25. CryoLife had never before instituted a nationwide QA Hold.

THE LIMITED DISCLOSURE OF THE QA HOLD

- 26. Although CryoLife's senior management told the company's customer service manager about the Recall Order, they decided to withhold news of the Recall Order from virtually all other CryoLife employees, and the public, until August 14, 2002.
- 27. Following senior management's instruction, the customer service manager told CryoLife's customer service and shipping departments that CryoLife had instituted its own nationwide QA Hold, and directed those employees to place a hold on all outbound tissue shipments and to begin recalling recently shipped tissue products that were either in transit or had already arrived at their destination.

- 28. The customer service representatives were further specifically told not to disclose to customers the reason behind what they were doing, *i.e.*, the QA Hold, and not to contact any of CryoLife's sales representatives, who were not to be told of the Company's shipping halt or recall efforts.
- 29. Although the two customer service representatives initially followed their instructions, they quickly grasped that the QA Hold was unprecedented for CryoLife and decided that they needed to inform those CryoLife sales representatives whose customers they were calling of both the QA Hold and the Company's efforts to halt, or obtain the return of, shipments.
- 30. When contacting the sales representatives, these customer service representatives never suggested that every CryoLife customer, including those not affected by the QA Hold, should be contacted.

DEFENDANTS LEARN ABOUT THE QA HOLD AND OR RECALL ORDER

- 31. On August 13, 2002, Defendants Drinen, Holmes and P. Nash were contacted by their customer service representative with a "911" designation as a signal of the importance of her message.
- 32. When Drinen, Holmes and P. Nash returned the calls, the customer service representative told them that CryoLife had instituted a nationwide QA Hold for an indefinite period, there would be no further shipments and previous shipments were being retrieved. She also told them that she was actively working to halt shipments and calling customers to request the return of unused products.

- 33. The customer service representative further explained to Drinen, Holmes and P. Nash that she was not supposed to be conveying this information to them, but that she was doing so as a courtesy because she had been instructed to call certain of their customers.
- 34. The customer service representative offered Drinen, Holmes and P. Nash the option of personally contacting those customers who were expecting shipments, to tell them that their shipments would not be coming.
- 35. Later that evening, CryoLife's Vice-President of Marketing discussed the QA Hold with P. Nash, telling P. Nash about the Recall Order and explaining that further information would be disclosed by CryoLife the next day.
- 36. The following morning as new customer service personnel reported for work, CryoLife senior management provided more information to the customer service personnel, telling them that the shipping halt had been imposed by the FDA, and allowing them to communicate that information to CryoLife sales representatives in the field.
- 37. Accordingly, a CryoLife customer service representative contacted T. McHugh in the morning of August 14, 2002, and told him that the FDA had imposed a shipping halt. The customer service representative further told T. McHugh that, while she did not want him to call all of his customers, she did want him to tell any customers who were expecting a shipment, or who might call to place an order, that no shipments would be made because the FDA had imposed a shipping halt.

38. In those instances where the Defendants actually contacted their customers, none of them told the customers about the reasons for the non-delivery, <u>i.e.</u>, the QA Hold or the Recall Order.

THE MARKET RESPONDS NEGATIVELY TO THE RECALL ORDER

- 39. On August 14, 2002, at approximately 12:07 p.m. ET, wire services began to carry stories about the Recall Order.
- 40. During the next twenty minutes, the share price of CryoLife's stock dropped from \$9.20 to \$5.50.
- 41. At 12:30 p.m. ET, the NYSE halted trading in CryoLife stock. At that time, the stock was down \$4.00 per share, a 42% decrease from the prior day's close of \$9.50 per share. The last trade in CryoLife stock on August 14, 2002 was at \$5.50 per share.
- 42. After the trading halt, CryoLife issued a press release that disclosed the Recall Order. The press release also disclosed that CryoLife had placed all related tissue in quarantine (i.e., a QA Hold), was withdrawing its financial guidance for the rest of 2002, and was evaluating the situation to determine its expected impact on CryoLife's business and operations.
- 43. During the afternoon of August 15, 2002, CryoLife stock reopened for trading at \$1.50 per share. After trading as low as \$1.40 per share, the stock closed at \$2.03 per share, a drop of \$3.47 per share (63%) from the closing price on August 14, 2002 and of \$7.47 per share (79%) from the August 13, 2002 closing price.

DEFENDANTS TRADE CRYOLIFE SECURITIES BEFORE THE MARKET RESPONDS TO THE RECALL ORDER

44. Each of the Defendants learned of the QA Hold, and traded CryoLife securities, before CryoLife disseminated this information to the investing public.

Drinen's Illegal Trading of CryoLife Stock

- 45. On August 14, 2002, between approximately 6:05 a.m. MT and 6:30 a.m. MT, Drinen placed orders to sell approximately 1,648 shares of CryoLife stock, which represented his entire CryoLife holdings.
- 46. Prior to placing his trades, Drinen called one of his stock brokers and discussed the execution price of his proposed trades in relation to a "big event" or "big news."
- 47. Before the QA Hold and Recall Order became public knowledge, Defendant Drinen sold his shares at approximately \$9.20 per share, providing him gross proceeds of approximately \$15,162.00, and allowing him to avoid losses of approximately \$11,816.00.

Holmes's Illegal Trading of CryoLife Stock

- 48. On August 14, 2002, beginning at approximately 8:55 a.m., Holmes placed orders to sell all of the CryoLife stock that he and his wife held, approximately 4,170.5 shares.
- 49. Before the QA Hold and Recall Order became public knowledge, Holmes sold these shares at prices ranging from approximately \$9.20 to \$9.39 per share, generating gross proceeds of approximately \$38,890.00, and allowing his wife and him to avoid losses of approximately \$30,424.00.

The McHughs' Illegal Trading of CryoLife Stock and Options

50. On August 14, 2002, T. McHugh tipped his wife, N. McHugh, about the QA

Hold.

- 51. Thereafter, but before the QA Hold and Recall Order became public knowledge, the McHughs sold approximately 1,578 shares of CryoLife stock, representing their entire CryoLife holdings. They also sold an additional 2,000 shares "short."
- 52. All of these shares were sold at prices ranging from approximately \$9.20 to \$9.41 per share.
- 53. In addition to dumping their entire CryoLife holdings and selling additional shares short before the QA Hold and Recall Order became public knowledge, the McHughs also purchased "30 August 10 PUT" options on CryoLife stock at \$1 per unit, for a total of approximately \$3,000. This transaction gave the McHughs the right to sell 3,000 shares of CryoLife stock at \$10 a share by or about August 17, 2002.
- 54. On August 15, 2002, the McHughs sold an equal amount of PUT options on CryoLife stock (i.e., "30 August 10 PUT" options) at \$7.50 per unit, to close out their option position from August 14, 2002.
- 55. By dumping their CryoLife shares, selling additional CryoLife shares "short," and purchasing PUT options on CryoLife stock before the QA Hold and Recall Order became public knowledge, the McHughs avoided losses and/or obtained ill-gotten gains totaling approximately \$46,381.

The Nashs' Illegal Trading of CryoLife Stock

56. On or around August 14, 2002, P. Nash tipped is wife, C. Nash about the QA Hold.

- 57. On August 14, 2002, beginning at approximately 6:05 a.m. MT, P. Nash and C. Nash placed orders to sell all of their CryoLife stock, approximately 6,577 shares.
- 58. These shares were sold before the QA Hold and Recall Order became public knowledge, at prices ranging from approximately \$9.20 to \$9.21 per share. The transactions generated gross proceeds of approximately \$60,512.00, and allowed the Nash's to avoid losses of approximately \$47,161.
- 59. In addition to selling his own CryoLife shares, on or around August 13, 2002, P. Nash also tipped his mother about the QA Hold, Recall Order and/or other non-public adverse information indicating that the value of CryoLife's stock price would drop significantly in the very near future.
- 60. As a result, P. Nash's mother sold all 75 shares of CryoLife stock, which she and her husband held, before the QA Hold and Recall Order became public knowledge.
 - 61. Prior to August 14, 2002, P. Nash's mother had never sold any stock.
- 62. As a result, P. Nash caused his mother to illegally avoid losses of approximately \$554.
 - 63. By tipping his mother, P. Nash is responsible for these losses avoided.

COUNT I

Violations of Section 17(a) of the Securities Act [15 U.S.C. 77q(a)]

64. Paragraphs 1 through 63 are hereby realleged and are incorporated herein by reference.

- 65. Defendants Drinen, Holmes, T. McHugh, N. McHugh, P. Nash and C. Nash during 2002, singly or in concert, in connection with the offer or sale of securities, by use of the means and instruments of transportation and communication in interstate commerce or by use of the mails,
 - (a) directly and indirectly employed devices, schemes and artifices to defraud purchasers of such securities;
 - (b) directly and indirectly obtained money or property by means of any untrue statement of a material fact or any omission to state a material fact necessary in order to make the statements made, not misleading; and/or
- (c) engaged in transactions, practices and a course of business which would have operated as a fraud or deceit upon the purchasers of such securities, all as more particularly described above.
- 66. Defendants Drinen, Holmes, T. McHugh, N. McHugh, P. Nash, and C. Nash knowingly, intentionally and/or recklessly engaged in the aforementioned devices, schemes and artifices to defraud. In engaging in such devices, schemes and artifices to defraud, Defendants acted with scienter, that is, with an intent to deceive, manipulate or defraud or with a severe reckless disregard of the fact that (a) their trading activity was based upon material non-public information, and (b) in trading they were breaching a fiduciary relationship or other relationship of trust or confidence, or had received the information from someone breaching such a duty.

67. By reason of the foregoing, Defendants Drinen, Holmes, T. McHugh, N. McHugh, P. Nash, and C. Nash, directly and indirectly, have violated, are violating and, unless restrained and enjoined, will continue to violate §17(a) of the Securities Act [15 U.S.C. § 77q(a)].

COUNT II

<u>Violations of Section 10(b) of the Exchange Act [15 U.S.C. 78j(b)] and Rule 10b-5</u> thereunder [17 C.F.R. 240.10b-5]

- 68. Paragraphs 1 through 63 are hereby realleged and are incorporated herein by reference.
- 69. Defendants Drinen, Holmes, T. McHugh, N. McHugh, P. Nash, and C. Nash, during 2002, singly or in concert, in connection with the purchase and sale of securities, directly and indirectly, by the use of means and instrumentalities of interstate commerce and by use of the mails:
 - (a) employed devices, schemes, and artifices to defraud;
 - (b) made untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading; and/or
 - (c) engaged in acts, practices, and courses of business which would and did operate as a fraud and deceit upon persons, in connection with the purchase and sale of such securities,

all as more particularly described above.

70. Defendants Drinen, Holmes, T. McHugh, N. McHugh, P. Nash, and C. Nash knowingly, intentionally, and/or recklessly engaged in the aforementioned devices, schemes and

artifices to defraud, made untrue statements of material facts and omitted to state material facts, and engaged in fraudulent acts, practices and courses of business. In engaging in such conduct, Defendants acted with scienter, that is, with an intent to deceive, manipulate or defraud or with a severe reckless disregard of the fact that (a) their trading activity was based upon material non-public information, and (b) in trading they were breaching a fiduciary relationship or other relationship of trust or confidence, or (c) had received the information from someone breaching such a duty.

71. By reason of the foregoing, Defendants Rodney R. Drinen, Gerald R. Holmes, Thomas P. McHugh, Nancy M. McHugh, Prescott B. Nash, and Christina H. Nash have violated, and unless restrained and enjoined, will continue to violate Section 10(b) of the Exchange Act [15 U.S.C. 78j(b)] and Rule 10b-5 thereunder [17 C.F.R. 240.10b-5].

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Commission, respectfully prays that the Court:

I.

Issue a permanent injunction enjoining Defendants Rodney R. Drinen, Gerald R. Holmes, Thomas P. McHugh, Nancy M. McHugh, Prescott B. Nash, and Christina H. Nash, and their agents, servants, employees, attorneys, and all persons in active concert or participation with him who receive actual notice of the order by personal service or otherwise, and each of them, from violating:

(a) Section 17(a) of the Securities Act [15 U.S.C. 77q(a)]; and

(b) Section 10(b) of the Exchange Act [15 U.S.C. 78j(b)] and Rule 10b-5 thereunder [17 C.F.R. 240.10b-5].

Π.

Issue an Order requiring Defendants Rodney R. Drinen, Gerald R. Holmes, Thomas P. McHugh, Nancy M. McHugh, Prescott B. Nash, and Christina H. Nash to disgorge all ill-gotten gains and losses avoided in connection with purchases and sales of CryoLife stock and stock options they made, or caused others to make, while they were in possession of material, nonpublic information as alleged in the Commission's Complaint, plus pay prejudgment interest thereon.

Ш.

Issue an Order pursuant to Section 21A of the Exchange Act [15 U.S.C. 78u-1] imposing a civil monetary penalty against Defendants Rodney R. Drinen, Gerald R. Holmes, Thomas P. McHugh, Nancy M. McHugh, Prescott B. Nash, and Christina H. Nash.

IV.

Retain jurisdiction over this action in order to implement and carry out the terms of all orders and decrees that may have been entered or to entertain any suitable application or motion by the Commission for additional relief within the jurisdiction of this Court.

V.

Grant such other and further relief as may be necessary and appropriate.

This 14 day of September, 2005,

RESPECTFULLY SUBMITTED,

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